REMARKS

Newly discovered references to Karaguezuian et al. and to Alferness et al. have been used in all of the rejections of the final Office action and to withdraw the allowance of claims previously allowed. The references previously used to reject these claims is no longer applied against any of the currently rejected claims. By this amendment applicants clarify the claimed subject matter over the newly cited references.

Claims 13, 14, 17 and 19 were rejected under 35 U.S.C. §102(b) and §103(a) in view of various combinations of US Pat. 5,403,353 (Alferness et al.), US Pat. 5,817,132 (Karaguezuian et al.) and US Pat. 5,824,033 (Ferrari). Amended Claim 13 describes a nonsurgical method of treating atrial fibrillation comprising transdermally receiving a cardiac signal from a patient by a transdermal electrode; determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; enabling a portable shock generator with a signal from the portable analyzer; receiving a shock command from an operator; and shocking the patient with the portable shock generator by means of the transdermal electrode in response to the shock command if the patient is experiencing atrial fibrillation. Unlike surgically implanted atrial defibrillators, this method determines the existence of atrial fibrillation transdermally with a portable external analyzer. If AF is found, a portable shock generator is enabled by a signal from the analyzer. This gives the operator such as the patient or a medical responder an opportunity to determine whether now is the appropriate time to shock the patient to end the AF. If it is, a shock command is received from the operator and the portable shock generator delivers the shock. No surgery is required and the patient need only be shocked at an appropriate time as determined by the operator.

The Alferness et al. patent shows a way to treat AF in post-heart surgery patients. Before the patient's chest is closed up, electrodes 42 and 52 are sutured to the pericardium and run through the chest wall where they, along with sensor electrodes 38 and 40 which have been left in contact with the myocardium, can be externally accessed by an external cardiovertor. When an ECG monitor detects AF, the cardiovertor is manually set up and actuated. See the

paragraph spanning columns 6-7. When cardioversion is no longer required the loose sutures are pulled to disengage the electrodes and the heart wires and cardioverting leads are pulled from the patient's chest (col. 8, lines 6-7). As is obvious, this is a very surgical procedure. In the method of Claim 13 the cardiac signal is obtained transdermally by means of a transdermal electrode, not one which is surgically attached to the heart and passes through the chest wall. If AF is found the portable shock generator is enabled with a signal from the portable analyzer. In the Alferness et al. method the setup and operation of the cardiovertor is entirely manual. The shock is delivered by the same transdermal electrode used to acquire the heart signals, not by implanted electrodes separate from invasive monitoring leads. For all of these reasons it is respectfully submitted that Claim 13 and its dependent Claims 18 and 19 are patentable over Alferness et al.

The Karaguezuian et al. patent describes an implanted defibrillator which analyzes heart signals with approximate entropy analysis. The implanted energy delivery system 106 applies a shock by means of therapy leads 107 on the surface or within the heart. In the background section of this patent, like the background section of the instant application, conventional implanted and external defibrillators are described. Fig. 2 shows the conventional external approach in which an ECG monitors heart activity and a defibrillating shock is provided by a manually programmed, AC-powered defibrillator which sits on a stand on the floor. In this conventional approach the ECG monitor and the floor-mounted defibrillator are completely independent. There is no portable shock generator which is enabled by a signal from a portable analyzer as recited in amended Claim 13. The defibrillator 60 in Karaguezuian et al. is not portable. For all of these reasons it is respectfully submitted that amended Claim 13 is patentable over Karaguezuian et al. or the combination of the two patents, as are dependent Claim 18 and 19.

Ferrari shows a conventional transcutaneous defibrillator electrode and provides none of the above-mentioned deficiencies of Alferness et al. and Karaguezuian et al. with respect to Claims 13, 18, and 19.

Claim 17 describes a nonsurgical method of treating atrial fibrillation, comprising transdermally receiving a cardiac signal from a patient; determining from the signal whether the patient is experiencing atrial fibrillation; applying a shock enable signal to a portable shock generator if the patient is experiencing atrial fibrillation; shocking the patient with the portable shock generator external to the patient if the patient is experiencing atrial fibrillation; and wherein the determining comprises determining the patient's heart rate and determining that the patient is not in atrial fibrillation if the heart rate is outside of a predetermined range. Unlike Alferness et al., the cardiac signal is received transdermally, not through a lead sutured to the pericardium and passing through the chest wall, and surgery is not required. Unlike Karaguezuian et al. no surgery is required and unlike the conventional defibrillator shown in Fig. 2 of Karaguezuian et al. a portable shock generator is used and a shock enable signal is applied to the portable shock generator. Ferrari only suggests the use of a standard defibrillator electrode. For these reasons it is respectfully submitted that Claim 17 is patentable over any combination of the newly cited references.

Amended Claim 14 describes a nonsurgical method of treating atrial fibrillation, comprising receiving a cardiac signal from a patient; determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; informing the patient by means of the analyzer that the patient is experiencing atrial fibrillation; receiving a shock command from an operator; and shocking the patient with a portable shock generator in response to the shock command if the patient is experiencing atrial fibrillation, further comprising: applying defibrillator pads to the patient; wherein the receiving comprises receiving the cardiac signal via the pads, and wherein the shocking comprises shocking the patient via the pads. Unlike Alferness et al. and Karaguezuian et al. Claim 14 describes a nonsurgical method whereas both of these patents are focused on surgical methods. Unlike any of the newly cited patents Claim 14 recites that the patient is informed by means of a cardiac signal analyzer that the patient is experiencing atrial fibrillation, thus allowing the patient to determine whether this is an appropriate time for treatment. Unlike the

conventional technique shown in Fig. 2 of Karaguezuian et al., a portable shock generator applies the shock if one is warranted. Ferrari only shows that defibrillator electrode pads are known. For all of these reasons it is respectfully submitted that Claim 14 is patentable over all of the newly cited patents.

In view of the foregoing amendment and remarks it is respectfully submitted that Claims 13, 14 and 17-19 presented above are patentable over any combination of Alferness et al., Karaguezuian et al. and Ferrari. Accordingly it is respectfully requested that the rejection of Claims 13 and 17-19 under 35 U.S.C. §102(b) and of Claim 14 under 35 U.S.C. §103(a) be withdrawn and that Claims 1-23 be passed on to issuance.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

GUST H. BARDY ET AL.

By: _____
W. Brinton Yorks, Jr.
Reg. No. 28,923

Philips Electronics
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7152
February 7, 2005